Memorandum

Subject	Date
Interim Policy for Scheduled Investigations (DFN: 601.02)	OCT 27 2009

To

Special Agents in Charge
Diversion Program Managers
Diversion ASACs
Diversion Group Supervisors
TDS Supervisors

From

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

The Office of Diversion Control is in the process of re-writing the Diversion Manual, the purpose of which is to refocus efforts within the program to ensure continued compliance among the registrant population.

Until such time as the manual is finalized, the attached interim guidelines will be implemented. It is the responsibility of all Diversion Program Managers and Diversion Group Supervisors to ensure the documented interim guidelines are incorporated into current and future investigations and work plans upon receipt of this memorandum.

Questions pertaining to these changes and requirements should be directed to ODG or your staff coordinator.

Attachments:

1. Interim Policy In Lieu of Diversion Manual Changes
2. ARCOS Preparation for On-Site Inspection with instructions (ODP)
3. CSOS Inspection Requirements

Attachment 1

Interim Policy in Lieu of Diversion Manual Changes

- **Automation of Reports and Consolidated Orders System (ARCOS) Analysis**: A complete and detailed ARCOS analysis will be conducted on every registrant engaged in ARCOS reportable activity during each scheduled investigation. Prior to the on-site portion of an investigation, Diversion Investigators must access and review ARCOS status and transaction activity as follows:
  - [redacted]
  - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
  - [redacted]
  - [redacted]
  - [redacted] (see Attachment #2).

- [redacted] (see Attachment #2).

- **Request for Validation of ARCOS Data**: All ARCOS data to be used in the course of the investigation is required to be validated by ODPT prior to the onsite portion of the investigation. [redacted]

- [redacted]

- **Drug Theft and Loss (DTL) Data**: Investigators will check drug theft and loss data (DEA Forms 106) online via the DTL data base prior to the site visit and determine if there are unexplained losses or any patterns involving theft or loss. Reports registrants have submitted to the field office should be in the DTL system; the investigator should verify that they are. If not, both should be included for accountability purposes. All reports of theft or loss should be verified while on site at the subject firm.

- **Memoranda of Agreement (MOA)**: The investigator will ascertain whether the subject firm's registration is currently under a Memorandum of Agreement, either as an individual registrant or as part of a larger corporation that has entered into an MOA. If so, the investigator will thoroughly review the details and conditions of the MOA prior to the onsite portion of the investigation.

- **Suspicious Order Reporting**: OD, in conjunction with CCD, has notified in writing, all distributors of their responsibility to immediately report all "Suspicious Orders." A suspicious order is an order, which, when received by a registrant and in accordance with 21 CFR 1301.74, the registrant determines to be suspicious. The registrant **does not fill** the order but reports same to their local DEA office. Excessive purchase reports from registrants (reports of unusual sales) **will no longer be accepted** by the DEA. Any firm still reporting excessive purchases will be informed of the OD directive and instructed to immediately report "Suspicious Orders."

- **Due Diligence**: Registrants must have established effective controls against diversion of controlled substances in accordance with 21 USC 823. DEA will not approve, certify, or assist registrants in conducting their due diligence responsibilities (e.g. provide lists or identify customers to whom they should or should not sell. It is solely incumbent upon the registrant to know their customers and the potential abuses of the controlled substance products for which they are approved. A registrant's due diligence process/program should be flexible to adapt to changing trends with respect to diversion. A thorough review of the registrant's due diligence procedures must be documented in the scheduled investigation report.

- **Verifications**:
  - Onsite verifications of the subject firm's customers will be conducted.
  - For those registrants that participate in the Controlled Substance Ordering System (CSOS), and whose customers that order via CSOS, it is imperative that the items provided separately for CSOS processing be verified during the inspection and verification process.
  - [redacted]
    - [redacted]
  - [redacted]
  - If the customer is not within the area of responsibility of the field office conducting the investigation, a Report of Investigation (DEA-6) will be forwarded to the appropriate field office requesting assistance in conducting the verification. Included within the body of the report, the investigator will provide to the field office of responsibility, the appropriate background information and necessary documents which led to the customer verification request.

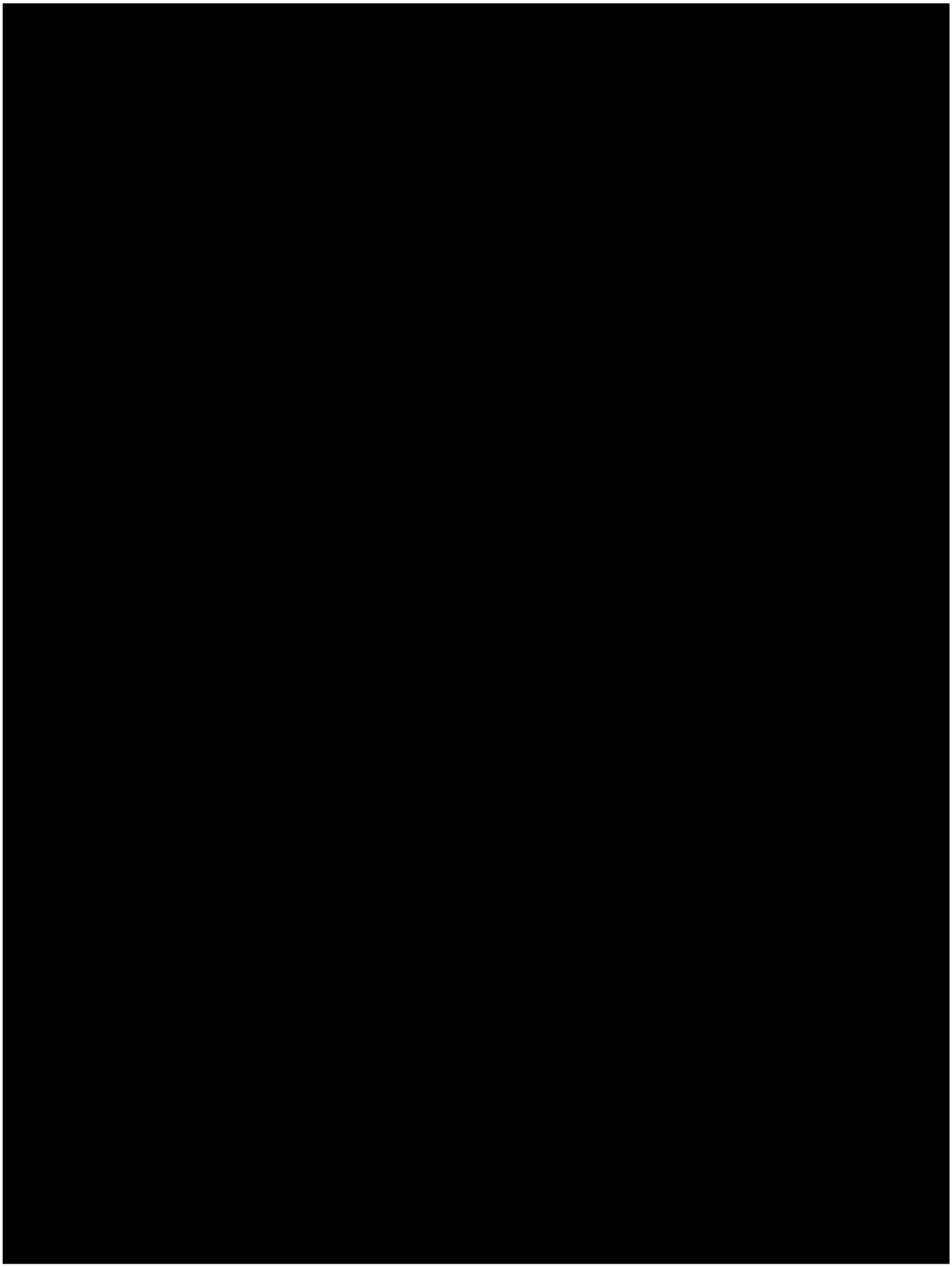
- **Intelligence Reporting**: Registrants in compliance with the specific responsibilities of due diligence and prevention of diversion of controlled substances will be able to provide varying degrees of intelligence.

- [redacted]
- [redacted]
- [redacted]
- [redacted]

The above suggested questions are presented as examples only. It is imperative that investigators have a thorough understanding of drug movement/purchase/sales of the subject firm. It is solely incumbent upon the registrant to provide verifiable and documented justification to any change in patterns and distributions of C/Ss. The final justification should be compared to the intelligence obtained during the subject firm's previous scheduled investigation. Substantial and continued growth in particular product lines should be evaluated with greater scrutiny.

- **Controlled Substance Ordering System (CSOS)**:
  - Investigators will coordinate with Headquarters Diversion Office of Technology (ODT) to determine if the registrant is a participant in CSOS. If so, a review of all CSOS orders and those items identified in Attachment 2, with special attention being given to the highlighted citations, will be reviewed with the subject firm or during the verification process.
- **Report Submission Format**: Field offices will be afforded the opportunity to submit their reports in one of two ways.

- The first option is to submit three (3) separate reports based upon which phase of the scheduled investigation is being reported. In the "Report Re:" the first report would be reported as "Scheduled Investigation [redacted] – Preparation, (DEA Registration Number)", the second report would be reported as "Scheduled Investigation [redacted] – On-Site Investigation (DEA Registration Number)", and the third report would be reported as "Scheduled Investigation [redacted] – Verifications".
- The second option is to submit one comprehensive report insuring that all the criteria of "preparation", "on-site", and "verifications" is contained in the report.
- Which ever option the reporting office chooses to submit their reports, all reports will contain all the criteria as outlined in subchapter 5253 of the Diversion Manual.



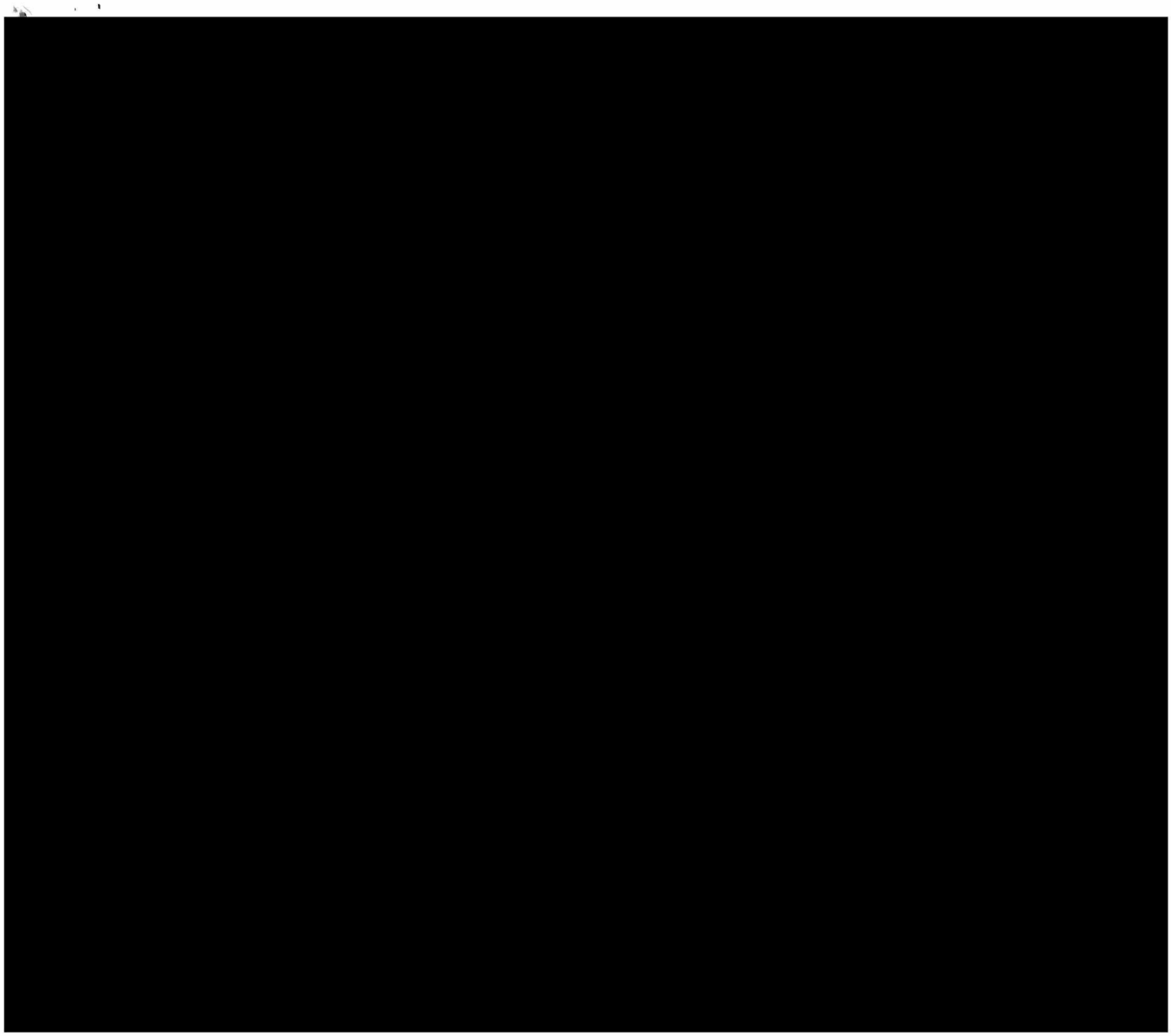
Drug Enforcement Administration, Office of Diversion Control,
Pharmaceutical Investigations Section, Targeting and Analysis Unit

General Instructions

NOTE: These guidelines are to help you prepare for an on-site cyclic investigation. It should be completed prior to your on-site visit.

[redacted]

Drug Enforcement Administration, Office of Diversion Control,
Pharmaceutical Investigations Section, Targeting and Analysis Unit



Attachment 3

CSOS Inspection Requirements

- **Suppliers:**
  - 1305.22(c)(2) and 1311.50(2). Has the supplier verified that the digital certificate has not expired?
  - 1305.22(c)(3) and 1311.50(3). Has the supplier verified the validity of the digital certificate by checking the Certificate Revocation Listing (CRL)? Does the supplier cache the CRL or conduct real time checks?
  - 1305.22(c)(4) and 1311.50(4). Has the supplier verified the customer's eligibility to order controlled substances Authority to Order Revocation Listing (ARL)?
  - 1305.22(d) and 1311.60(a). Does the supplier retain all CSOS orders with associated linked records for two years?
  - 1305.22(e). Did the supplier fill any partially filled CSOS orders beyond the 60 days following the date of the original CSOS order?
  - 1305.24(a). Does the supplier have a central processing center for CSOS orders?
  - 1305.24(a)(1). Do CSOS orders reflect which registered location was assigned which line item to fill?
  - 1305.24(a)(2). Did the central records facility create a record linked to the original CSOS order noting which items the registered location was to fill.
  - 1305.25(b). Does the supplier have on file, records of CSOS orders which were rejected or refused and the reason for rejection or refusal?
  - 1305.26(c). If the supplier recovers a lost CSOS order and also receives a second CSOS order from the purchaser, did the supplier notify the purchaser and indicate "Not Accepted"?
  - 1305.27(b). Does the supplier have on file, for each filled CSOS order, the original order record and all linked statements?
  - 1305.27(c). If the supplier has all CSOS orders maintained on a central server, are those records readily retrievable at the registered location?
  - 1305.28(a) and (c). If the supplier voided any particular line items on the original CSOS order, did the supplier indicate on the linked record to the purchaser, that nothing was shipped for each item voided?
  - 1305.29. Does the supplier provide the DEA with electronic copies of filled CSOS orders or an electronic report of the orders filled in a format that the DEA has specified, within two business days?
  - 1311.55(d). Has an independent (third party) audit been conducted on the software being utilized by the supplier and provided to its customers (purchasers)?
  - 1311.60(b). Are all electronic records easily readable or easily rendered into a format that a person can read?

- **Purchasers**:

  - 1305.22(g). Has the purchaser created a record of the quantity of each item received and the date received? Is this record linked to the original order and archived?
  - 1305.25(c). Does the purchaser have on file and linked to their original CSOS order, notification of rejection or refusal with explanation?
  - 1305.26(a). Does the purchaser have on file, any signed statements of notification to their suppliers of any lost CSOS orders?
  - 1305.26(b). Did the purchaser create another order to replace a previously lost order? Was this CSOS order linked to the original lost order? Does the replacement order also have linked the notification as specified by 1305.26(a)?
  - 1305.27(a) and 1311.60(a). Does the purchaser, for each CSOS order filled, have on file the original signed order with all linked records? Are these filled CSOS orders maintained for two years? Does the purchaser also have on file all copies of each unaccepted or defective order and associated linked statements?
  - 1305.28(b). Does the purchaser maintain electronic copies of voided orders from the supplier?
  - 1311.15(b). Is there more than one person at the registered location who is authorized to make CSOS orders? Are the subordinate CSOS authorized personnel limited to particular schedules for ordering purposes?
  - 1311.20(a). If there is more than one person at the registered location placing CSOS orders, identify who the CSOS coordinator is?
  - 1311.30(c). Dose anyone else have use of the private key (digital signature) besides the person authorized?
  - 1311.30(d). Has the person authorized made a backup copy of their private key?
  - 1311.30(e). Has any individual authorized to place CSOS orders and who suspected or had their private key lost, stolen, or comprised report it to the DEA?
  - 1311.45(a)(1). Has the CSOS coordinator reported to the DEA within six hours a person authorized by power of attorney and possessing a digital signature authority, leaving the employ of the institution?
  - 1311.45(a)(2). Has the CSOS coordinator reported to the DEA within six hours, any person authorized by power of attorney and possessing digital signature authority, who has had their privileges revoked?
  - 1311.45(a)(3). Does the CSOS coordinator maintain a record that lists each person granted power of attorney to sign controlled substance orders?
  - 1311.60(b). Are all electronic records easily readable or easily rendered into a format that a person can read?
  - 1311.60(c). Is there on file, copies of the subscriber agreement, signed by each CSOS certificate holder?

- **Terms and Definitions**:
    - 1311.02 defines most terms used within these regulations.
    - Link(ed): A record associated with an original and specific CSOS order, which is electronically attached to the original CSOS order record. Linked (attached) records are maintained under the same requirements and standards as the original CSOS order.